Can transcranial direct current stimulation reduce hemispatial neglect? A study of ipsilateral activation and contralateral inhibition

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The proposed study aims to test the acute effects of tDCS on chronic hemispatial neglect. In this particular application of tDCS the damaged hemisphere will be activated and the healthy hemisphere inhibited.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON40009

Source
ToetsingOnline

Brief title
Transcranial direct current stimulation as treatment for neglect

Condition

- Central nervous system vascular disorders

Synonym
hemispatial neglect, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: subsidie van de Hersenstichting

Intervention

Keyword: attentional deficits, Electrical stimulation, Stroke

Outcome measures

Primary outcome

The current study aims to assess the short-term effects of bilateral tDCS on chronic neglect. We anticipate that this type of stimulation will result in a larger reduction in the attentional imbalance between the two cerebral hemispere compared to placebo treatment. This will be measured using the conventional subtests of the Behavioural inattention test. (BIT).

Secondary outcome

In addition, possible long-term effects (after four weeks) of repeated stimulation will be investigated, together with a generalisation to sensorimotor function and activities of daily living (ADL). This will be assessed using the BIT, line bisection, Gainotti copying task, pressure sensitivity (von Frey hairs), finger position sense (somatosensory function), finger tapping (motor control) and the Barthel Index (ADL function).

Study description

Background summary

A common deficit after stroke is hemispatial neglect. These patients ignore stimuli on the contralesional side. Neglect is related to reduced functional recovery and therefore it is important to develop effective treatment methods. The proposed study will test a new method that is based on the idea that neglect is a consequence of a imbalance between the attentional systems of the two hemispheres. This model suggest that each cerebral hemisphere focuses

attention to the contralateral side of space. In neglect the attentional system of the undamaged hemisphere dominates. To reduce this imbalance transcranial direct current stimulation (tDCS) will be used. This method, that has been proven to be safe, consists of a weak electrical current between two electrodes on the skull that influences brain activity. One advantage of tDCS that so far has not been investigated is that it allows simultaneously to activate the attentional system in the damaged hemisphere and to inhibit the attentional system in the healthy hemisphere. We anticipate that this bilateral stimulation will result in a smaller imbalance between the two attentional systems and a larger reduction of neglect symptoms than after single site stimulation.

Study objective

The proposed study aims to test the acute effects of tDCS on chronic hemispatial neglect. In this particular application of tDCS the damaged hemisphere will be activated and the healthy hemisphere inhibited.

Study design

Each participating patient will commence with a baseline assessment. Two weeks later treatment will be started. This will consist of two periods of treatment: tDCS stimulation and placebo stimulation. In each period patients will be given daily sessions of 20 minutes of stimulation on five consecutive days. The order of the placebo and tDCS treatment periods will be counterbalanced across patients. The two treatment periods will be separated by a period of four weeks without treatment. The placebo condition will be indistinguishable from the tDCS condition for the patient. tDCS and placebo treatment will be double blind. During each stimulation period (placebo and tDCS) the patients will be assessed before and after each stimulation session of 20 minutes on the conventional subtests of the BIT. Assessment and treatment will be performed at Utrecht University or at the patient's home (depending on the patients ability to visit the university regularly).

Intervention

Bilateral transcranial direct current stimulation (tDCS)

Study burden and risks

Each patient will be seen at four different times.
1. Baseline assessment
2. After twee weeks: tDCS or placebo stimulation (five consecutive days)
3. After another four weeks the other stimulation condition (five consecutive days)
4. Follow-up assessment (four weeks after treatment cessation)

At the start of tDCS participants often feel a slight itch which disappears in about one minute. The risks of tDCS are negligible. Investigations of the possible effect of treatment on neglect can only be assessed in a group of hemispatial neglect patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Left hemispatial neglect after right hemispheric lesions. This will be verified using CT and/or MRI scans
Age: >18 years
Right handed
At least 4 months after CVA, based on study of Nijboer et al., 2013 Cortex.

Inclusion till Sept 1st 2014

Exclusion criteria

Language and communication deficits,
Evidence of bilateral cortical damage
Epilepsy
psychiatric disturbances and/or alcohol/drug addiction
Eczema on head skin, damage of head skin
Metal in head

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-11-2011
Enrollment:	16
Type:	Actual

Ethics review

Approved WMO Date:	16-02-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-11-2011

Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-11-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	18-01-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	16-10-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	02-01-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-09-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	08-09-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL34655.041.10